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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/374,117	08/16/1999	NICHOLAS F. FORTE	PM-251091	3340

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EXAMINER

ROCHE, LEANNA M

ART UNIT	PAPER NUMBER
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1771

DATE MAILED: 01/31/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

MF=14

Office Action Summary

Application No.

09/374,117

Applicant(s)

FORTE, NICHOLAS F.

Examiner

Leanna Roche

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 November 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-29 and 32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-29 and 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>13</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendments filed November 9, 2001 have been entered and carefully considered. The amendments included in the substitute specification are sufficient to overcome the previous objection, in Paper No. 11, to the specification for the inclusion of improperly identified trademarks. Therefore, this objection to the specification has been withdrawn.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 26 and 32 are rejected under 35 U.S.C. 102(e) as being anticipated by McCormack et al. (USPN 6075179).

McCormack is directed to breathable, multi-layer films which may be antimicrobial and provide a barrier to liquids. The core layer of McCormack (reads on

Applicant's D layer) is comprised of a porous, breathable, moisture vapor permeable film which acts to adhere two outer layers together to form an overall liquid impermeable composite. The skin layers of McCormack (reads on Applicant's C layers) are comprised of sheets of hydrophilic polymeric material, such as polyesters and vinyl alcohols, which may be substantially free of particulate filler and which are water vapor permeable, antimicrobial and liquid impermeable. The three films of McCormack are coextruded so that the outer skins are bonded to the core in a complete and uniform manner.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Langley (USPN 5560974) in view of Reed et al. (USPN 5653699), substantially as set forth in Paper No. 11.

This explanation is provided as clarification of the previous rejections in Paper Nos. 6 and 11. Langley discloses a breathable, multi-layer composite which provides a barrier to pathogens and blood and other biological fluids. Langley discloses a core layer of a microporous film which exhibits water vapor permeability and impermeability to the passage of liquids. This microporous film may be thermally bonded on both sides

to non-woven web layers. By thermal bonding, the microporous film layer acts as an adhesive core layer. Therefore, the microporous film layer of Langley reads on Applicant's D layer.

Langley, however, uses nonwoven webs instead of outer monolithic **film** layers containing a hydrophilic polymeric resin. Reed discloses a composite structure comprised of a relatively thin film layer of continuous, monolithic, hydrophilic, polymeric material substantially free of particulate filler. The monolithic material of Reed possesses a differential moisture vapor transmission rate and is impermeable to liquids and bacteria. This reads on Applicant's C layer. It is known in the art that films provide a better barrier to liquid than nonwoven web materials (see USPN 5695868 Column 2, lines 7-8). Therefore, it would have been obvious to the skilled artisan at the time this invention was made to combine the teachings of Langley and Reed, motivated by the desire to produce the laminate structure of Langley with the most optimal barrier to penetration by liquids.

Langley discloses an outer layer (C) with a weight from about 0.2 to 2.5 oz/y² and a microporous film layer with a weight of 0.85 oz/y², but neither Langley nor Reed specifically disclose Applicant's claimed volume ratios. However, it would have been obvious to one having ordinary skill in the art at the time this invention was made to produce a composite film with layers which fall into Applicant's claimed volume ratios, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. See *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). In the present case, it would have been obvious to optimize the volume

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ratio of the composite film to obtain a film which is cost effective in that the most expensive material is used in the least volumetric proportion.

6. Claims 26-29 rejected under 35 U.S.C. 103(a) as being unpatentable over McCormack et al. (USPN 6075179).

McCormack discloses the claimed invention but does not specifically disclose Applicant's claimed volume ratios. However, it would have been obvious to one having ordinary skill in the art at the time this invention was made to produce a composite film with layers which fall into Applicant's claimed volume ratios, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. See *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). In the present case, it would have been obvious to optimize the volume ratio of the composite film to obtain a film which is cost effective in that the most expensive material is used in the least volumetric proportion.

7. Claims 26-29 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCormack et al. (USPN 6075179) in view of Reed et al. (USPN 5653699).

This rejection is provided as an alternative to the rejections set forth in paragraphs 3 and 6 above. McCormack is directed to breathable, multi-layer films which may be antimicrobial and provide a barrier to liquids. The core layer of McCormack (reads on Applicant's D layer) is comprised of a porous, breathable, moisture vapor permeable film which acts to adhere two outer skin layers together to form an overall liquid impermeable composite. The three films of McCormack are

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coextruded so that the outer skins are bonded to the core in a complete and uniform manner.

McCormack does not use the specific terminology monolithic, hydrophilic and particulate free, in describing their skin layers. However, Reed discloses a composite structure comprised of a relatively thin film layer of continuous, monolithic, hydrophilic, polymeric material substantially free of particulate filler. The monolithic material of Reed possesses a differential moisture vapor transmission rate and is impermeable to liquids and bacteria. This reads on Applicant's C layer. The monolithic layer of Reed is known to produce visually clear films. This would allow the production of a laminate wherein the color of the core material is visible. It would have been obvious to the skilled artisan at the time this invention was made to combine the teachings of McCormack and Reed, motivated by the desire to produce the laminate structure of McCormack so that the color of the overall laminate structure appears as the color of the core layer.

McCormack in view of Reed discloses the claimed invention but neither reference specifically discloses Applicant's claimed volume ratios. However, it would have been obvious to one having ordinary skill in the art at the time this invention was made to produce a composite film with layers which fall into Applicant's claimed volume ratios, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. See *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). In the present case, it would have been obvious to optimize the volume ratio of the composite film to obtain a film which is cost effective in that the most expensive material is used in the least volumetric proportion.

Response to Arguments

8. Applicant's arguments filed November 9, 2001 have been fully considered but they are not persuasive.

9. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

10. Applicant's arguments with regard to Langley in the response of June 12, 2001 are not persuasive because Langley was not relied upon to disclose the claimed outer monolithic layers. As is clarified above, Langley was relied upon to disclose a breathable, multi-layer composite which provides a barrier to pathogens, blood and other biological fluids, which is moisture vapor permeable and liquid impermeable, and which is comprised of an adhesive, microporous core layer having two outer layers adhered thereto. Langley was also not been relied on here to show coextrusion. Therefore, Applicant's arguments with regard to Langley are not found persuasive.

11. With regard to Reed, Applicant argues that the exudates transport layer of Reed does not read on Applicant's D layer. This is not found persuasive because Reed has not been relied on to show Applicant's D layer. Reed was relied on by the examiner to show Applicant's C layer, as is discussed above. Therefore, Applicant's arguments with regard to the exudates layer of Reed are not found persuasive.

12. Applicant also argues that Reed does not show coextrusion. This argument is not found persuasive in view of the new rejections because Reed has not been relied on here to show coextrusion.

13. Applicant argues that Reed's single monolithic film is 10 times the thickness of the monolithic layers of Applicant's invention because Applicant's invention shows a total thickness of less than 1 mil. This is not found persuasive because Reed discloses monolithic film layers of as little as 0.1 mils.

14. The arguments with respect to claim 32 have been considered, but are moot in view of the new grounds of rejection.

15. Additionally, with regards to any arguments that have not been directly addressed, they have been found moot in view of the new ground(s) of rejection.

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See McCormack USPN 5695868 with regards to the use of films instead of nonwoven webs.

17. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leanna Roche whose telephone number is 703-308-6549. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm (with alternate Mondays off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Blaine Copenheaver can be reached on 703-308-1261. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Imr
January 24, 2002


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